

REMARKS

Reconsideration of the pending application is respectfully requested on the basis of the following particulars.

1. Objection to the drawings

Rejection of claim 24 under 35 U.S.C. § 112, first paragraph

Claim 24 is now canceled which renders the objection to the drawings, and the rejection under 35 U.S.C. § 112, first paragraph moot.

2. In the claims

In the amendment to the claims, claims 1, 12 and 21 are amended to explicitly recite features of the wound dressings of these claims.

Specifically, these claims are amended to recite that the wound dressing has proximal and distal sides, and that the facing layer is directly secured to the absorbent core. The adhesive layer is now described as being directly applied to the facing layer so as to surround the region of the plurality of apertures. Lastly, the claims now make explicit the previously implicit feature that the facing layer and the adhesive layer are contiguous and combine to define the proximal side of the dressing.

Claims 1 and 12 are amended to recite that the facing layer includes a cross-linked silicone gel.

Support for the amendment to these claims is found in Figs. 9 and 10, and the corresponding description in the specification on page 12, 3rd full paragraph.

Claims 11 and 24 are canceled without prejudice or disclaimer.

New claim 25 is submitted which recites essentially the subject matter of original claim 21 with the added distinction that the proximal side of the dressing consists both the at least one localized segment of the adhesive layer and at least one exposed region of the facing layer.

Entry of the amendment to claims 1, 12 and 21, and new claim 25 is respectfully requested.

3. Rejection of claims 1-10 and 12-20 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent application publication 2003/0199800 (*Levin*) in view of U.S. patent 6,566,575 (*Stickels*)

This rejection is respectfully traversed in view of the amendment to claims 1 and 12, from which the remaining claims of this rejection depend, on the basis that the proposed combination of *Levin* and *Stickels* fails to render claims 1 and 12 *prima facie* obvious. In particular, the proposed combination of *Levin* and *Stickels* fails to possess every limitation required by the rejected claims, and further one skilled in the art would not be motivated by the teachings of *Levin* and *Stickels* to modify the teachings of these patent references to make the claimed wound dressing.

Turning first to *Levin*, it is readily apparent that this publication does not meet all of the limitations of amended claims 1 and 12.

In observing Fig. 3, *Levin* clearly shows the adhesive surface (40) as only being deposited on the plastic film (36). Nowhere is there any depiction or teaching of the adhesive surface (40) being applied directly to the gel cushioning layer (22). In fact, *Levin* clearly indicates in paragraph [0022] that it is the adhesive surface (40) and not the cushioning layer (22) which secures the bandage (20) against a wound.

Next, *Levin* fails to disclose providing a facing layer that is “skin-adherent” and is separate from an adhesive layer, as required by the rejected claims. Instead, the cushioning layer (22) is provided merely as its name indicates: a “cushioning” layer. There is no description in *Levin* which would tend to hint that the cushioning layer is a skin adherent gel. Further, there is a noticeable distinction in *Levin* of the adhesive surface, which is provided to releasably secure the dressing against a wound, and the cushioning layer which is provided to absorb compressive forces applied against the bandage ([0022]).

With the cushioning layer, *Levin* appears to teach away from the claim construction of the wound dressing according to claims 1 and 12 since the cushioning layer (22) is only described as being used to absorb forces. It follows that one skilled in the art would likely consider the cushioning layer (22) of *Levin* not to have skin adherent properties because if it did, it would be pressed into the wound and stick to the wound thereby causing trauma to the patient wearing the dressing.

From the aforementioned discussion on *Levin*, it is readily evident from Fig. 3 that the adhesive surface (40) and cushioning layer (22) of *Levin* are not contiguous and do not combine to define to the entirety of the proximal side of the dressing. Instead, there is a clearly defined gap between the adhesive surface (40) and the cushioning layer (22) that is not filled by either the adhesive surface (40) or the cushioning layer (22).

Lastly, *Levin* does not disclose or even hint at securing the cushioning layer (22) to the absorptive layer (26). Instead, *Levin* inflexibly teaches that the absorptive layer (26) rests on the plastic film (36) located in between the cushioning layer (22) and the absorptive layer (26) (Fig. 3; [0023]). As discussed in paragraph [0024] of *Levin*, the absorptive layer (26) is separately removable from the plastic film (36).

Having established that *Levin* fails to disclose or suggest all of the features required by claims 1 and 12, the discussion now turns to *Stickels* which clearly does not make up for all of the shortcomings of *Levin*.

The rejection relies on *Stickels* as a prior art teaching that discloses that it would be known to provide a pressure sensitive layer to the proximal surface of a facing layer. The combination of *Levin* with *Stickels*, however, would not motivate one skilled in the art to make the dressing of amended claims 1 and 12, and the proposed combination of the teachings of *Levin* and *Stickels* would not lead one skilled in the art to make the claimed wound dressing of amended claims 1 and 12.

As indicated above, both claims 1 and 12 indicate that the adhesive layer surrounds the apertured region of the facing layer, and that the facing layer and the

adhesive layer are contiguous and combine to define the entirety of the proximal surface of the wound dressings of these claims. *Stickels* clearly teaches providing an adhesive layer (26) that constitutes the entirety of the facing layer (20). Moreover, there is no disclosure of the adhesive layer (26) of *Stickels* as surrounding the apertured region (24) of the facing layer (20). Thus, even if *Levin* is combined with *Stickels*, these two references would not teach all of the required limitations of claims 1 and 12.

In further observations, *Levin* describes the facing layer (20) as being a thin conformable polymeric film (col. 9, line 66 through col. 10, line 14). Thus, the facing layer (20) of *Stickels* is not skin adherent, and does not comprise a cross-linked silicone gel, as specifically required by claims 1 and 12. Hence, there is clearly no support for the notion in either *Levin* or *Stickels*, of directly applying an adhesive layer on a facing layer that is skin adherent. This particular technical effect is both novel and non-obvious in view of the combined teachings of *Levin* and *Stickels*.

Next, one skilled in the art would not be motivated to modify *Levin* with the teachings of *Stickels* since this would require the cushioning layer (22) to be completely covered, with the exception at the apertures, with the adhesive surface (40). There is no support in *Levin* of providing the cushioning layer (22) with the adhesive surface (40), and it would be highly undesirable since the cushioning layer (22), which is in direct contact with the wound ([0022]), would then stick to the wound when the cushioning layer is compressed since the adhesive layer is pressure sensitive.

In view of these observations, it is readily observed that the proposed combination of *Levin* and *Stickels* fails to disclose or suggest every limitation required by pending claims 1 and 12. As such, these claims are patentable. Withdrawal of the rejection of these claims is respectfully requested.

4. Rejection of claims 1 and 11 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent application publication 2003/0199800 (*Levin*) in view of U.S. patent 6,103,369 (*Lucast*)

Claim 1 is now the only claim of this rejection since claim 11 has been canceled.

This rejection is respectfully traversed on the basis that *Lucast* fails to make up for the shortcomings in the teachings of *Levin*. Therefore, the proposed combination of *Levin* and *Lucast*, does not amount to a *prima facie* case of obviousness. The shortcomings of *Levin* are addressed in detail in section (3) of these remarks in reference to the rejection based on *Levin* and *Stickels*.

Turning to *Lucast*, this patent fails to disclose or suggest a facing layer that comprises a cross-linked silicone gel. Instead, as identified in the action, *Lucast* teaches that a facing layer may be used which “is a gel-adhesive composite comprising a pressure sensitive adhesive, a hydrocolloid, and a swelling agent” and “the gel-adhesive may be a broad variety of adhesives which may uniformly disperse a gel therein.” (col. 7, lines 6-18). It is readily understood that a cross-linked silicone gel is hydrophobic and is not a hydrocolloid gel. As such, a cross-linked silicone gel would not be appropriate for use in the gel-adhesive composite described by *Lucast*.

Next, it will be pointed out that there is no discussion in *Lucast* of providing an adhesive layer that surrounds a region of apertures on the aforementioned facing layer, such that the facing layer and the adhesive layer are contiguous and combine to define to the entirety of the proximal side of the dressing. One skilled in the art would readily recognize that a facing layer comprising a cross-linked silicone gel is distinguished from the facing layer of *Lucast*, such as in layers (20), (34), and (44), which has a high moisture transmission rate. Because the facing layer of *Lucast* inherently has a high moisture transmission rate, the location of the adhesive layer is irrelevant which is contrary to the construction in the pending claims which requires that the adhesive layer only surround the region of apertures..

In the pending claims, the facing layer includes the through extending apertures because the cross-linked silicone gel itself does not have a sufficient moisture transmission rate. As such, the specification explains that the apertures are molded into the silicone gel so as to permit the transfer of exudate through the facing layer (page 10, 1st and 2nd paragraphs). Thus, amended claim 1 requires that the adhesive layer surround the apertures of the facing layer, and one skilled in the art would not perceive such a specific construction from the teachings of *Levin* and *Lucast*.

In view of these observations, it is submitted that the proposed combination of *Levin* and *Lucast* fails to disclose or suggest every limitation required by amended claim 1. Accordingly, withdrawal of this rejection is respectfully requested.

5. Rejection of claims 21-23 under 35 U.S.C. § 103(a) as being unpatentable over U.S. patent application publication 2003/0199800 (*Levin*) in view of U.S. patent 5,540,922 (*Fabo*) and in view of U.S. patent 6,103,369 (*Lucast*)

This rejection is respectfully traversed on the basis that *Fabo* fails to make up for the shortcomings of the proposed combination of *Levin* and *Stickels*. Therefore, the proposed combination of *Levin*, *Fabo* and *Stickels*, does not amount to a *prima facie* case of obviousness. The shortcomings of *Levin* and *Stickels* are addressed in detail in section (3) of these remarks. The remainder of these remarks will treat the shortcomings of *Fabo*.

From the basis for this rejection, it is assumed that the rejection proposes replacing the compressive layer (22) of *Levin* with a silicone gel of the type used in *Fabo*. However, such a proposed combination would not work and does not find a basis in these patents themselves.

It is pointed out that the silicone gel of *Fabo* would not be suitable as the cushioning layer (22) of *Levin* since *Fabo* admits that the strength of a silicone gel (3) used therein is inherently weak and requires a textile material (2) for reinforcement (col. 2, lines 20-35; lines 58-63). Thus, the silicone gel of *Fabo* would not adequately

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absorb compressive forces applied to the wound, as required by the cushioning layer(22) of *Levin*.

As with *Levin* and *Stickels*, *Fabo* does not teach directly applying an adhesive layer on a facing layer that is skin adherent. Thus, particular technical effect is both novel and non-obvious in view of the combined teachings of *Levin*, *Fabo* and *Stickels*.

Because the proposed combination of *Levin*, *Stickels* and *Fabo* does not possess all of the features required by the rejected claims, it is submitted that this combination of prior art fails to render the rejected claims *prima facie* obvious. Accordingly, withdrawal of this rejection is respectfully requested.

6. Conclusion

As a result of the amendment to the claims, and further in view of the foregoing remarks, it is respectfully submitted that the application is in condition for allowance. Accordingly, it is respectfully requested that every pending claim in the present application be allowed and the application be passed to issue.

If any issues remain that may be resolved by a telephone or facsimile communication with the applicants' attorney, the examiner is invited to contact the undersigned at the numbers shown below.

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Date: August 25, 2006

Respectfully submitted,



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